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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.      | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------|------------------|
| 10/070,574   | 11/12/2002  | Dietmar Becher       | 07038-0004UI             | 6881             |
| 23859  | 7590        | 08/24/2005           | EXAMINER                 |                  |
| NEEDLE & ROSENBERG, P.C.<br>SUITE 1000<br>999 PEACHTREE STREET<br>ATLANTA, GA 30309-3915 |             |                      | KATCHEVES, KONSTANTINA T |                  |
|  |             |                      | ART UNIT                 | PAPER NUMBER     |
|  |             |                      | 1636                     |                  |

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/070,574

Applicant(s)

BECHER ET AL.

Examiner

Konstantina Katcheves

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,4-7 and 17-20 is/are allowed.
- 6) ☒ Claim(s) 2,3,8-16,21 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

Claims 1-22 are pending in the present application.

### ***Response to Arguments***

The rejection of claims 4-7 and 17-20 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement has been withdrawn in view of Applicant's arguments that the plasmids and organisms of the claim have been deposited according to the rules of 37 CFR 1.801-1.809.

Claims 2, 3, 8-16, 21 and 22 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons already of record and those set forth below.

Applicant has not presented any new unrebutted arguments; however, the reasoning of each of the prior office actions is repeated herein in response to Applicant's arguments. Applicant's arguments in response to the written description rejection over the nucleotides 1-1134 of SEQ ID NO:1 or a part thereof and the written description rejection over the SEQ ID NO:2 or a part thereof are the same. In the interests of compact prosecution and brevity, these arguments are addressed together.

Applicant's arguments are based on three points: (1) that the parts of nucleotides 1-1134 of SEQ ID NO:1 and the parts of SEQ ID NO:2 are parts of a specifically defined sequence; (2) that Applicants have provided a functional limitation for the claimed subsequences; (3) that clear guidance is provided for screening for the claimed function.

Art Unit: 1636

With regard to Applicant's positions above, the subsequences that are parts of the claimed sequences are vast such that Applicant fails to adequately described the genus that has the claimed function. The fact that a complex computer algorithm can determine many structures does not mean Applicant has identified a correlation between structure and the function. As discussed in the prior Office action, MPEP 2163(I)(A) clearly addresses this issue:

A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

A generic statement . . . without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function." See *University of California v. Eli Lilly and co.* 119 F.3d 1559, 43 USPQ2d 1398 (1997) ("*Lilly*"). Applicant has provided a "biomolecule" sequence, a "functional characteristic" and "a method for obtaining the claimed sequence," *i.e.* screening for either promoter activity for the parts of SEQ ID NO:1 or terminator activity for the parts of SEQ ID NO:2. However, According to MPEP 2163(I)(A) a "known or disclosed correlation between the function and the structure" is required. See also *Lilly*.

More recent decisions have held to the position set forth in *Lilly* and the MPEP. The Court in *University of Rochester v. G.D. Searle & Co.* 69 USPQ2d 1886, 1893 (Fed. Cir. 2004) ("*Rochester*") discussing their decision in *Enzo Biochem., Inc. v. Gen-Probe Inc.*, 323 F.3d 956 63 USPQ2d 1609 (Fed Cir 2002) states that:

functional descriptions of genetic material can in, some cases, meet the written description requirement if functional characteristics are 'coupled with a known or disclosed correlation

Art Unit: 1636

between function and structure, or some combination of such characteristic' (quoting from the PTO's Guidelines for the Examination of Patent Applications Under the 35 USC 112, P1, 'Written Description Requirement', 66 Fed. Reg. 1099, 1106) [emphasis added].

Applicant has not made the correlation between the structure of those "parts" of the sequences claimed and function of those parts. Applicant has not disclosed what structural features of nucleotides 1-1134 or 572-1134 of SEQ ID NO:1 are required for the subsequences, *i.e.* "parts," to function as promoters. Applicant has also failed to disclose what structural features of parts of SEQ ID NO:2 are required for terminator activity. Applicant has also failed to disclose identifying characteristics in terms of a consensus sequence, domain, etc. of the claimed sequences to lead on of skill in the art to reasonably conclude that Applicant was in possession of the claimed invention such that the written description requirement would have been satisfied.

Applicant also refers to Example 15 the "Revised Written Description Guidelines Training Materials" in support of his position. The examiner is aware of the guidelines referred to by Applicant. However, Applicant should note that these are merely guidelines, and they do not have the force and effect of law. As discussed above, the present rejection is consistent with and supported by recent case law, decided after implementation of the guidelines. Moreover, the guideline even support the examiners position as is evident from the discussion of *Rochester* above which quotes form the guidelines.

***Allowable Subject Matter***

Claims 1, 4-7 and 17-20 allowed.

Art Unit: 1636

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1636

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves  
Examiner  
Art Unit 1636



JAMES KETTER  
PRIMARY EXAMINER